K041762

AUG - 6 2004

510(K) SUMMARY

SPONSOR

Guidant Corporation
Cardiac Rhythm Management (CRM)
4100 Hamline Avenue North
St. Paul, Minnesota 55112-5498

CONTACT PERSON

Jennifer X. Tang,
Phone: 800-CARDIAC or direct 651-582-6746
Fax: 651-582-5134
jennifer.tang@guidant.com

DATE OF THE SUMMARY

June 28, 2004

PREDICATE DEVICE

- Stylet Accessory, K905674, cleared on 1/30/1991
- HI TORQUE WHISPER Guide Wire, K023300, cleared on 10/28/2002

DEVICE TRADE NAME

Finishing Wire® SUPPORTRAK®

DEVICE COMMON NAME

Finishing Wire

DEVICE DESCRIPTION

The SUPPORTRAK Finishing Wire is intended to facilitate the positioning of a Guidant over-the wire left ventricular coronary venous pace/sense lead. The finishing wire is inserted into the lumen of the implanted lead and serves to stabilize the lead as the guide catheter is removed. A mechanical stop engages with the terminal pin of the lead and controls the position of the wire relative to the lead.

Each finishing wire model is specific to a particular lead length and hence, the location of the mechanical stop along the core wire varies for each SUPPORTRAK model. Also, the proximal end of the wire is formed into a loop to prevent incorrect insertion of the finishing wire in the lumen of the lead.

INTENDED USE

The SUPPORTRAK Finishing Wire is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Comparisons of the SUPPORTRAK Finishing Wire and the predicate devices show that the technological characteristics such as Intended Use, Material, Assembly, Design, Package, and Sterilization are substantially equivalent to the currently marketed predicate devices.

TESTING DATA

Testing demonstrated that the SUPPORTRAK Finishing Wire met the acceptance criteria. No new safety or effectiveness issues were raised during the testing program. The SUPPORTRAK Finishing Wire may be considered substantially equivalent to the predicate devices.

CONCLUSION

The Guidant SUPPORTRAK Finishing Wires are substantially equivalent to the currently marketed Stylet Accessory (K905674, cleared 1/30/1991) and HI TORQUE WHISPER Guide Wire (K023300, cleared 10/28/2002).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 6 2004

Guidant Corporation
c/o Ms. Jennifer X. Tang
Senior Regulatory Affairs Associate
Cardiac Rhythm Management
4100 Hamline Avenue North
St. Paul, MN 55112-5798

Re: K041762
Trade Name: SUPPORTRAK Finishing Wire, Models 6681-85 and 6667-69
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: II (two)
Product Code: DQX
Dated: June 29, 2004
Received: June 30, 2004

Dear Ms. Tang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041762

Device Name: Finishing Wire

Indications For Use:

The SUPPORTRAK Finishing Wire is intended to aid in the placement of a Guidant implantable coronary venous lead in the coronary venous vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041762